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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/956,925	09/21/2001	Hideaki Yagi	Q66253	2471

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EXAMINER

RAGONESE, ANDREA M

ART UNIT PAPER NUMBER

3743

DATE MAILED: 01/12/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/956,925

Applicant(s)

YAGI ET AL.

Examiner

Andrea M. Ragonese

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 12 October 2004.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,5-10,12,14-22,24-28,30 and 32 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,5-10,12,14-22,24-28,30 and 32 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

DETAILED ACTION

Response to Amendment

1. The After Final amendment, filed on May 10, 2004, was entered and Applicant was notified by the mailing of Advisory Action on June 29, 2004. Examiner acknowledges that **claims 1, 9, 30 and 32** were amended and **claims 29 and 31** were canceled.

2. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on July 12, 2004 has been entered.

3. The amendment, filed on October 12, 2004, has also been entered. Examiner acknowledges that **claims 1, 5 and 6** have been amended and **claim 4** has been canceled.

Response to Arguments

4. Applicant's arguments with respect to **claims 1, 5-10, 12, 14-22 and 24-28** have been considered but are moot in view of the new ground(s) of rejection.

Double Patenting

5. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent

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and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

6. A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

7. Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

8. **Claims 1, 5-10, 12, 14-22, 24-28, 30 and 32** are provisionally rejected under the judicially created doctrine of double patenting over claims 1-17 of copending Application No. 09/957,030. This is a provisional double patenting rejection since the conflicting claims have not yet been patented.

9. The subject matter claimed in the instant application is fully disclosed in the referenced copending application and would be covered by any patent granted on that copending application since the referenced copending application and the instant application are claiming common subject matter, as follows: oxygen supply apparatus with a sensor for detecting a state of breathing of a user.

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10. Furthermore, there is no apparent reason why applicant would be prevented from presenting claims corresponding to those of the instant application in the other copending application. See *In re Schneller*, 397 F.2d 350, 158 USPQ 210 (CCPA 1968). See also MPEP § 804.

11. **Claims 1, 5-10, 12, 14-22, 24-28, 30 and 32** are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims of U.S. Patent No. 6,837,244 B2. Although the conflicting claims are not identical, they are not patentably distinct from each other because the claims in both the application and the patent are drawn to oxygen supply apparatus with a sensor for detecting a state of breathing of a user. The use of the specific operating parameters are claimed in the patented claims would be obvious in order for the apparatus to deliver a specific flow of respiratory gas to a patient.

Claim Rejections - 35 USC § 102

12. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

13. **Claims 1, 5-8, 25, 27 and 30** are rejected under 35 U.S.C. 102(b) as being anticipated by Chua et al. (US 5,735,268). Chua et al. discloses an oxygen enriching apparatus **10** comprising: an oxygen outlet for supplying the oxygen-enriched gas to an inhalator **50** of the user **14**, and a breath detection port provided separately from the oxygen outlet and connected to the inhalator **50** for detecting the user's state of

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breathing; and a sensor **32** for detecting the user's state of breathing disposed on a flow passage **53** reaching the breath detection port, as shown in Figure 1.

Claim Rejections - 35 USC § 103

14. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

15. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

16. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

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17. **Claims 9, 10, 12, 14, 16, 24, 26, 28 and 32** are rejected under 35 U.S.C. 103(a) as being unpatentable over Chua et al. (US 5,735,268), as applied to **claims 1, 5-8, 25, 27 and 30** above, in view of Hete et al. (US 6,123,074). Chua et al. discloses an apparatus **10** operated by a controller **34** comprising all the limitations recited in **claims 9, 10, 12, 14, 16, 24, 26, 28 and 32**, with the exception of a means for controlling the oxygen-enriched gas at a first flow rate during the inhalation period and at a second flow rate during the exhalation period and a third flow rate during breath synchronization. While controller **34** is fully capable of being programmed to do this function, it is not specifically recited that presently it is programmed to do this function. However, this respiratory gas delivery method was known at the time the invention was made. Specifically, Hete et al. teaches the use of means for providing oxygen-enriched gas at a flow rate able the average continuous flow rate during inhalation and decreasing the flow of gas below the average flow rate to the patient during exhalation (column 8, line 66 through column 9, line 27). Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the apparatus of Chua et al. by adding the disclosed means for controlling gas flow to the user to provide oxygen-enriched gas at first, second and third flow rates corresponding to the IPAP, EPAP and average continuous flow rates because it is well known in the art, as taught by Hete et al., to use these different types of flow rates in order to make the user more comfortable.

18. **Claim 15** is rejected under 35 U.S.C. 103(a) as being unpatentable over Chua et al. (US 5,735,268), as applied to **claims 1, 5-8, 25, 27 and 30** above, in view of

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Kobatake et al. (US 5,720,276). Chua et al. discloses an apparatus **10** comprising all the limitations recited in **claim 15**, with the exception of an oxygen enriching section with a tank provided in an oxygen-enriched-gas supply passage on the downstream side. However, this type of oxygen-enriching set-up was known at the time the invention was made. Specifically, Kobatake et al. teaches the use of a nitrogen absorber **12f** in conduit **12i**, which is downstream of oxygen tank **12h** for enriching the oxygen by removing any nitrogen (column 3, lines 38-63), as shown in Figure 2. Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the apparatus of Chua et al. by adding the oxygen enriching section downstream of the oxygen supply tank because it is well known in the art, as taught by Kobatake et al., to use a nitrogen absorber in order to provide the patient with the highest concentration of oxygen in the respiratory gas.

19. **Claims 17 and 21** are rejected under 35 U.S.C. 103(a) as being unpatentable over Chua et al. (US 5,735,268) in view of in view of Kobatake et al. (US 5,720,276), as applied to **claim 15** above, and further in view of Davenport (US 6,237,594 B1). Chua et al. discloses an apparatus **10** comprising all the limitations recited in **claims 17 and 21**, with the exception of a plurality of tanks in series in the oxygen-enriched gas supply passage. However, the use of a plurality of tanks in an oxygen supply device was known at the time the invention was made. Specifically, Davenport teaches the use of a number of tanks **46, 50** to enable the apparatus to deliver a broad range of flow to the patient without negatively impacting the performance of the valves or sensors. Check valve **62** is provided between the tanks **46, 50** (column 5, lines 60-68). Therefore, it

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would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the apparatus of Chua et al. by including additional tanks in the gas supply lines because it is well known in the art, as taught by Davenport, in order to allow the apparatus to deliver gas over a wide range of flow rates without negatively impacting the performance of the valves and sensors.

20. **Claims 18 and 22** are rejected under 35 U.S.C. 103(a) as being unpatentable over Chua et al. (US 5,735,268) in view of Hete et al. (US 6,123,074), as applied to **claims 9, 10, 12, 14, 16, 24, 26, 28 and 32**, and further in view of Kobatake et al. (US 5,720,276), as applied to **claim 15** above, and further in view of Davenport (US 6,237,594 B1). Chua et al. discloses an apparatus **10** comprising all the limitations recited in **claims 18 and 22**, with the exception of a plurality of tanks in series in the oxygen-enriched gas supply passage. However, the use of a plurality of tanks in an oxygen supply device was known at the time the invention was made. Specifically, Davenport teaches the use of a number of tanks **46, 50** to enable the apparatus to deliver a broad range of flow to the patient without negatively impacting the performance of the valves or sensors. Check valve **62** is provided between the tanks **46, 50** (column 5, lines 60-68). Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the apparatus of Chua et al. by including additional tanks in the gas supply lines because it is well known in the art, as taught by Davenport, in order to allow the apparatus to deliver gas over a wide range of flow rates without negatively impacting the performance of the valves and sensors.

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21. **Claim 19** is rejected under 35 U.S.C. 103(a) as being unpatentable over Chua et al. (US 5,735,268) in view of in view of Kobatake et al. (US 5,720,276), and further in view of Davenport (US 6,237,594 B1), as applied to **claims 17** and **21** above. Chua et al. discloses an apparatus **10** comprising all the limitations recited in **claim 19**, but does not expressly disclose the size of the tanks. At the time of the invention was made, it was well known that the greater the size of the buffer tanks, the greater the efficiency in delivering a gas to a patient over a wide range of flow rates. Therefore, it would have been obvious to one having ordinary skill in the art to modify the tanks to have a capacity of at least 500 ml each as Applicant has done. Moreover, Applicant has not asserted that the specific size of the tanks recited provides a particular advantage, solves a stated problem or serves a purpose different from that of a tank under 500 ml, thus the use of this tank size lacks criticality in its utilization. One of ordinary skill in the art, furthermore, would have expected Applicant's invention to perform equally well with any size tanks because respiratory gas would still be provided to the patient. Therefore, it would have been obvious to modify the apparatus of Chua et al. by altering the tanks to have a capacity of at least 500 ml each because it is well known in the art to provide this capacity in order to efficiently provide the range of desired flow rates.

22. **Claim 20** is rejected under 35 U.S.C. 103(a) as being unpatentable over Chua et al. (US 5,735,268) in view of Hete et al. (US 6,123,074), and further in view of in view of Kobatake et al. (US 5,720,276), and further in view of Davenport (US 6,237,594 B1), as applied to **claims 18** and **22** above. Chua et al. discloses an apparatus **10** comprising all the limitations recited in **claim 20**, but does not expressly disclose the size of the

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tanks. At the time of the invention was made, it was well known that the greater the size of the buffer tanks, the greater the efficiency in delivering a gas to a patient over a wide range of flow rates. Therefore, it would have been obvious to one having ordinary skill in the art to modify the tanks to have a capacity of at least 500 ml each as Applicant has done. Moreover, Applicant has not asserted that the specific size of the tanks recited provides a particular advantage, solves a stated problem or serves a purpose different from that of a tank under 500 ml, thus the use of this tank size lacks criticality in its utilization. One of ordinary skill in the art, furthermore, would have expected Applicant's invention to perform equally well with any size tanks because respiratory gas would still be provided to the patient. Therefore, it would have been obvious to modify the apparatus of Chua et al. by altering the tanks to have a capacity of at least 500 ml each because it is well known in the art to provide this capacity in order to efficiently provide the range of desired flow rates.

Conclusion

23. Any inquiry concerning this communication or earlier communications from the examiner should be directed to **Andrea M. Ragonese** whose telephone number is **571-272-4804**. The examiner can normally be reached on Monday through Friday from 9:00 am until 5:00 pm.

24. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Henry A. Bennett can be reached on 571-272-4791. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

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25. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

AMR

January 10, 2005

Henry Bennett
Supervisory Patent Examiner
Group 3700